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First Named Inventor Wang et al.

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Remarks

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Firm Name	Bell, Boyd & Lloyd LLC		
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Printed name	Robert M. Barrett		
Date	December 11, 2006	Reg. No.	30,142

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Wang et al.
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Filed: September 14, 2006
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Art Unit: Unknown
Examiner: Unknown
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SUBMISSION OF CERTIFIED COPY OF PRIORITY DOCUMENT

Applicants are respectfully enclosing the certified copy of the priority document for which priority is claimed for the above-identified application under 35 U.S.C. §119. Specifically, the document enclosed is:

<u>Document No.</u>	<u>Country</u>	<u>Date</u>
04006639.1	Europe	March 19, 2004

The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY

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Dated: December 11, 2006

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Bescheinigung

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Die angehefteten Unterlagen stimmen mit der ursprünglich eingereichten Fassung der auf dem nächsten Blatt bezeichneten europäischen Patentanmeldung überein.

The attached documents are exact copies of the European patent application described on the following page, as originally filed.

Les documents fixés à cette attestation sont conformes à la version initialement déposée de la demande de brevet européen spécifiée à la page suivante.

Patentanmeldung Nr. Patent application No. Demande de brevet n°

04006639.1

Der Präsident des Europäischen Patentamts;
Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets
p.o.

R C van Dijk

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Bezeichnung der Erfindung/Title of the invention/Titre de l'invention:
(Falls die Bezeichnung der Erfindung nicht angegeben ist, siehe Beschreibung.
If no title is shown please refer to the description.
Si aucun titre n'est indiqué se référer à la description.)

Delivery of functional ingredients

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Delivery of functional ingredients

The present invention relates to a primary composition comprising all essential nutrients of a fruit or a plant material, which has an increased stability, bioavailability and miscibility; and process of forming the same. It also relates to an oral composition that contains the primary composition in a foodstuff, in a food supplement, in a cosmetic preparation or in a pharmaceutical preparation.

Background of the invention

Pigments and bioactive compounds extracted from fruits or plant materials are widely used in the food industry as functional ingredients. Among all of them, wolfberry (*Lycium barbarum*) is one of the most valued functional ingredients in China, especially for its benefits for eyesight and immuno-stimulation, associated with the multiple bioactive compounds present in the fruit. It is traditionally consumed through hot water extraction.

Many other ingredients are also well perceived by consumers for their beneficial properties, but their applications in food products are either difficult or give poor bioavailability. In fact, fruits are usually rich in reducing sugars, making the drying and handling of their powder very difficult.

A large number of extraction techniques are already known. For example, in WO03020053, a process for extracting carotenoids from carotenoid-containing plant matter is described. It comprises (i) Mixing the plant matter with water to achieve Brix not greater than 10 DEG . (ii) Crushing the mixture from stage (i) and separating the solids from the liquid to obtain two phases, pulp and serum. (iii) Extracting the pulp to obtain carotenoid-containing plant oleoresin. Such a water extraction technique is natural, but is not as efficient as compared to the use of a solvent.

For example, US 6648564 describes a process for forming, isolating and purifying xanthophyll crystals by saponification of a xanthophyll diester-containing plant extract in a composition of propylene glycol and aqueous alkali to form xanthophyll crystals. The substantially pure xanthophyll crystals so obtained are suitable for human consumption and can be used as a nutritional supplement and as an additive in food. However, solvent extraction techniques are more difficult to handle, and using solvent can impair the natural image and/or nutritional functions of the product.

Moreover, conventional extraction techniques usually extract a few compounds of the plant or fruit material, leaving some other bioactive compounds in the rest. For example, polysaccharides, polyphenols and other non lipophilic compounds are not extracted together with the lipophilic components such as carotenoids, lipophilic vitamins and other lipids.

For example, US 6409996 B1 describes a method of obtaining a composition comprising one or more flavonoids by treating a flavonoid containing raw material with an aqueous extraction medium to obtain an extract and separating the flavonoids from said extract by absorption and/or adsorption. Again such extraction method only gives an extract mainly containing a part of bioactive principles of the raw material.

It is thus an object of the present invention to address the above problems by providing a formulation for extracting and delivering the multi-nutrients from a fruit or a plant material with improved stability, miscibility, dispersibility in aqueous systems and bioavailability of the bioactive compounds. It is also an object to provide a primary composition that can be used directly or easily concentrated or dried into powder for applications in food products, nutritional supplements, cosmetic or pharmaceutical preparations.

Summary of the invention

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Accordingly, it is a first object of the invention to provide a miscible primary composition comprising at least the essential lipophilic and hydrophilic bioactive components of a whole fruit, vegetable and/or plant material, excluding insoluble fibers, in a milk or milk protein-containing carrier.

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Advantageously, the primary composition has a close profile of the essential active components of whole fruit, it has a good stability, miscibility and dispersibility in aqueous systems. Moreover, the primary composition has an enhanced nutritional value, in the form of a better bioavailability and stability. It has a pleasant taste and colour. It can be used directly or concentrated or dried into powder for several applications into daily-consumed food products or other nutritional uses.

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Accordingly, in a further object the primary composition is as an additive in a foodstuff for oral administration, such as in a nutritional composition, a food supplement, a pet food product, a cosmetic preparation or in a pharmaceutical preparation. The primary composition is also an additive in a product for topical application such as cosmetics or pharmaceutical products.

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The invention also relates to methods of forming the primary composition. The process for preparing the primary composition to deliver the essential lipophilic and hydrophilic bioactive components of a whole fruit, vegetable and/or plant material comprises the steps of:

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- i) mixing and milling the fruit, vegetable and/ or plant material in milk or milk protein-containing liquid medium,
- 25 ii) separating insoluble fibers to obtain an aqueous suspension
- iii) optionally pasteurising the resulting suspension
- iv) and further optionally drying the suspension to obtain a powder.

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The process has the major advantage of being natural and cost effective enabling improved delivery of multi-nutrients in the form of a combination of stabilized water- and fat-soluble compounds, free of organic solvent residues.

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In a further aspect, the invention provides a method for increasing miscibility or dispersibility in an aqueous system, stability, and bioavailability of bioactive compounds of a fruit, vegetable and/or a plant material using a process as described above. In particular, by using milk or milk proteins for extracting and delivering the multi-nutrients of functional ingredients of a fruit, a vegetable and/or a plant material.

It is another object of the invention to provide the use of a primary composition as described above, for delivering the multi-nutrients of functional ingredients of fruits, vegetables and/or plant materials with improved bioavailability, miscibility and stability.

It is a further object to provide the use of a primary composition as described above for the preparation of an oral, cosmetic or pharmaceutical composition intended for improving skin health, in particular for photoprotection of the skin or for protecting skin tissue against ageing.

It is still a further object to provide the use of a primary composition as described above for the preparation of an oral, topical or pharmaceutical composition intended for eye health.

Finally, the invention also provides the use of a primary composition as described above for the preparation of a food or pharmaceutical composition intended for stimulating the immune system.

The present invention now makes available to the consumer an improved composition obtained from natural products. It provides a primary composition retaining the important bioactive components of a fruit or a plant material or mixture thereof. Its profile of the bioactive components is close to that naturally occurred in the fruit or the plant material. The primary composition provides bioactive compounds of fruit or plant material, in a particularly highly bioavailable, stable and miscible form.

The features of the present invention can be best understood together with further objects and advantages by reference to the following description.

Detailed description of the invention

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Within the following description, the term bioactive compound is understood to mean molecules or components showing biological activity or health impact when orally ingested or applied in cosmetics.

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According to the first object, a miscible primary composition comprising at least the essential lipophilic and hydrophilic bioactive components of a whole fruit, vegetable and/or plant material, excluding insoluble fibers, in a milk or milk protein-containing carrier, is concerned.

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In a preferred embodiment, the fruit, vegetable and/or plant material may be in the form of vegetables, leaves, flowers, fruits, seeds and other parts of the plant, or a mixture thereof.

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In a preferred embodiment, berries or any other flavonoid-, polyphenol- or carotenoid-rich fruit or vegetable or seeds are selected. For example, berries such as wolfberry, blueberry, cranberry mulberry, blackberry, gooseberry, white currant, blackcurrant, red currant, raspberry, strawberry, arbutus berry or grapes and other fruits such as apples, melons, kivi, cherries, prunes, peaches, persimmons, citrus fruits such as mandarin, orange, tangerine, grapefruit, for example, may be used. Vegetables such as

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tomato, spinach, celery, carrots, pea, kale, parsley, watercress, cabbage, broccoli, lettuce, brussels sprouts, collard greens, turnip greens fennel, onions. Seeds such as corn, black rice, cocoa, and ingredients such as tea, thyme, sweet red pepper, for example, may also be used.

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Fruits, vegetables or plant materials may be used in the form of fresh, concentrated or dried materials, for example, air or freeze dried material.

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The essential bioactive components of fruit, vegetable or plant material may comprise lipids, alkaloids, proteins, carbohydrates, carotenoids, polyphenolic compounds such as flavonoids, and vitamins or minerals, for example. In particular, the bioactive compounds may be flavonoids such as flavones (e.g. apigenin, luteolin or diosmetin), flavonols (e.g. quercetin, myricetin, kaempferol), flavanones (e.g. naringenin, hesperidin), catechins (e.g. epicatechin, gallocatechin), anthocyanidins (e.g. pelargonidin, malvidin, cyanidin) or isoflavones (e.g. genistein, daidzein); carotenoids such as carotenes and xanthophylls (e.g. lycopene, carotene, phytofluene, phytoene, canthaxanthin, astaxanthin, beta-cryptoxanthin, capsanthin, lutein, zeaxanthin, or those in the form of fatty acid esters; carbohydrates (e.g. lycium barbarum polysaccharide); vitamins (e.g. vitamin C, B, E...); minerals (e.g. selenium, calcium, magnesium, potassium).

The primary composition contains at least the essential bioactive components of a whole fruit, vegetable and/or plant material, excluding insoluble fibers, in a milk or milk protein-containing carrier. The milk carrier may be in the form of skimmed milk or whole milk from animal or plant origin. In a more preferred embodiment, cow's milk or soymilk are used, depending on the fruit or primary composition which is desired. The milk-containing carrier may be any edible liquid containing milk proteins such as caseins or whey proteins, for example. Vegetable oils may optionally be added to the liquid medium.

The fruit, vegetable or plant material as described above, is mixed and milled in said milk or milk protein-containing liquid medium in a respective ratio of about 1:1 to 1:1000, preferably from 1:5 to 1:50. The mixing and milling step may be carried out at a temperature of from 1 to 95°C, preferably from about 20 to 80°C and more preferably from 40 to 80°C. Then, insoluble fibers are removed to obtain an aqueous suspension. This can be done by any conventional method. The resulting primary composition may be further pasteurized and/or dried into a powder by techniques known in the art. The primary composition obtained may also be in liquid or gel form.

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5 The present invention thus provides a primary composition having a similar profile of the important nutrients as whole fruit, it has a good stability, miscibility and bioavailability. These compositions may be highly dispersible in an aqueous system, if the powder form is chosen. In this instance, the powder is dispersible in cold or hot water.

10 The composition additionally comprises one or more of emulsifiers, stabilizers, antioxidants and other additives. Use is made of emulsifiers compatible in food, such as phospholipids, for example lecithin, polyoxyethylene sorbitan mono- or tristearate, monolaurate, monopalmitate, mono- or trioleate, a mono- or diglyceride. Use may also be made of any type of stabilizer that is known in food, in cosmetics or in pharmaceuticals. Use is made of any type of antioxidants that is known in food, in cosmetics or in pharmaceuticals. Use is made, as additives, of flavorings, colorants and any other additive known in food, in cosmetics or in pharmaceuticals. These emulsifiers, stabilizers, antioxidants and additives are added according to the final use of the primary composition.

20 According to a further aspect, the present invention relates to an oral composition comprising the primary composition described above in a foodstuff, in a food supplement, in a pet food product, in a cosmetic preparation or in a pharmaceutical preparation.

25 In a preferred embodiment, a food composition for human consumption is supplemented by the above primary composition. This composition may be a nutritional complete formula, a dairy product, a chilled or shelf stable beverage, a mineral or purified water, a liquid drink, a soup, a dietary supplement, a meal replacement, a nutritional bar, a confectionery, a milk or a fermented milk product, a yoghurt, a milk based powder, an enteral nutrition product, an infant formula, an infant nutritional product, a cereal product or a fermented cereal based product, an ice-cream, a chocolate, 30 coffee, a culinary product such as mayonnaise, tomato puree or salad dressings or a pet food.

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In this case, the primary composition, which is preferably in the form of a powder, can be dispersed in the above-mentioned foods or drinks so as to have a daily intake in bioactive nutrients as described above, which depends mainly on the fruit, vegetable or plant utilized, the desired effect and target tissue. The amount of the primary composition or food composition to be consumed by the individual to obtain a beneficial effect will also depend upon its size, its type, and its age.

The nutritional supplement for oral administration may be in capsules, gelatin capsules, soft capsules, tablets, sugar-coated tablets, pills, pastes or pastilles, gums, or drinkable solutions or emulsions, a syrup or a gel, with a dose of about 0.1 to 100% of the primary composition, which can then be taken directly with water or by any other known means. This supplement may also include a sweetener, a stabilizer, an antioxidant, an additive, a flavoring or a colorant. A supplement for cosmetic purpose can additionally comprises a compound active with respect to the skin. Methods for preparing them are common knowledge.

In another embodiment, a pharmaceutical composition can be administered for prophylactic and/or therapeutic treatments. In therapeutic applications, compositions are administered to a patient already suffering from a disease, as described herein under, in an amount sufficient to cure or at least partially arrest the symptoms of the disease and its complications. An amount adequate to accomplish this is defined as "a therapeutically effective dose". Amounts effective for this will depend on the severity of the disease and the weight and general state of the patient. In prophylactic applications, compositions according to the invention are administered to a patient susceptible to or otherwise at risk of a particular disease. Such an amount is defined to be "a prophylactic effective dose". In this use, the precise amounts again depend on the patient's state of health and weight.

The compounds of the invention are preferably administered with a pharmaceutical acceptable carrier, the nature of the carrier differing with the mode of

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administration, for example, enteral, oral and topical (including ophthalmic) routes. The desired formulation can be made using a variety of excipients including, for example, pharmaceutical grades of mannitol, lactose, starch, magnesium stearate, sodium saccharin, cellulose, magnesium carbonate. This composition may be a tablet, a capsule, a pill, a solution, a suspension, a syrup, a dried oral supplement, a wet oral supplement.

It will be appreciated that the skilled person will, based on his own knowledge select the appropriate components and galenic form to target the active compound to the tissue of interest, e.g. the skin, colon, stomach, kidney or liver, taking into account the route of administration.

The invention also relates to a cosmetic composition comprising the primary composition described above. It may be formulated in lotions, shampoos, creams, sun-screens, after-sun creams, anti-ageing creams and/or ointments, for example. This composition which can be used topically additionally comprises a fat or an oil which can be used in cosmetics, for example those mentioned in the CTFA work, Cosmetic Ingredients Handbook, Washington. It is also possible to add other cosmetically active ingredients. The composition additionally comprises a structuring agent and an emulsifier. Other excipients, colorants, fragrances or opacifiers can also be added to the composition. It will be appreciated that the present cosmetic products will contain a mixture of different ingredients known to the skilled person, ensuring a fast penetration of the said substance into the skin and preventing degradation thereof during storage.

It will be understood that the concept of the present invention may likewise be applied as an adjuvant therapy assisting in presently used medications. Since the compounds of the present invention may easily be administered together with food material special clinical food may be applied containing a high amount of the said substances. It will be clear that on reading the present specification together with the appending claims the skilled person will envisage a variety of different alternatives to the specific embodiments mentioned herein.

Administering to a pet or human, a food, nutritional supplement, a cosmetic or pharmaceutical composition as described above, results in an improved skin health, in particular for photoprotection of the skin or for protecting skin tissue against ageing, e.g. for inhibiting damage to the skin and/or mucous membranes by inhibiting collagenases and enhancing the synthesis of collagen. In fact, the use of the primary composition as described above makes it possible to enhance the bioavailability of the said bioactive compounds in the body and to slow down the ageing of the skin, for example. It may also be useful in the prevention or treatment of sensible, dry or reactive skins, or for improving skin density or firmness.

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The primary composition as described above may also be used for the preparation of an oral, topical or pharmaceutical composition for eyesight, in particular for reducing risk of cataract and macular degeneration. It can be used also for preventing or treating cardiovascular diseases or disorders or cancers and stimulating the immune system, for example.

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The following examples illustrate the invention in more detail without restricting the same thereto. All percentages are given by weight otherwise indicated.

20 **Examples**

Example 1: Preparation of the primary composition from wolfberry

Dried wolfberry fruits (40 g) and whole milk (300 g) were introduced in a 1-liter container. The mixture was kept to stand for 10 minutes and treated with Polytron (Dispersing and Mixing Technology by KINEMATICA, PT3000) at 26000 rpm for 15 minutes under a nitrogen atmosphere. During the Polytron-treatment the temperature of the mixture was maintained at 80-85°C by means of water bath and cooled to room temperature afterwards. The resulting mixture was then centrifuged at 2000G for 10 minutes. The solid residue is discarded. The liquid phase (306g of orange-yellow milk)

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was freeze dried. The dried product is finally grinded to give 54 g of orange-yellow powder.

Example 2: Preparation of the primary composition from tomato

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Fresh tomato pulp (93g), skimmed milk powder (10g) and tap water (30 g) were introduced in a 250-ml container. The mixture was homogenized (Polytron) at 26000 rpm for 10 minutes under a nitrogen atmosphere. The temperature of the mixture was maintained below 30°C by cooling with an ice bath. The mixture was then centrifuged
10 at 2000G for 10 minutes. The solid residue was discarded and the liquid phase (96g of a red-pink milk) was freeze dried. The dried product was finally grinded and a red-pink powder (17.5g) was obtained.

Example 3: Dairy product containing primary composition according to the invention

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The primary composition as prepared in example 1, is used for the manufacture of fermented yogurt-like milk products. To do this, 1L of a milk product containing 2.8 % of fats and supplemented with 2 % of skimmed milk powder and 6 % of sucrose was
20 prepared, pasteurized and its temperature then lowered to 42°C. Precultures of a non-thickening strain of *Streptococcus thermophilus* and of a non-viscous strain of *Lactobacillus bulgaricus* were reactivated in a sterile MSK culture medium containing 10% of reconstituted milk powder and 0.1% of commercial yeast extract. The
25 pasteurized milk product is then inoculated with 1% of each of these reactivated precultures and this milk product was then allowed to ferment at 32°C until the pH reached a value of 4.5. To the fermented milk, yogurt-like product, the primary composition as in example 1 (1%) was added and stored at 4°C.

Example 4: Pet food product

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A feed mixture was made up of corn, corn gluten, chicken and fish, salts, vitamins and minerals. The moistened feed leaving the preconditioner was then fed into

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an extruder-cooker and gelatinised. The gelatinised matrix leaving the extruder was forced through a die and extruded. The extrudate leaving the die head was cut into pieces suitable for feeding to dogs, dried at about 110°C for about 20 minutes, and cooled to form pellets. The resulting water activity of the pellets was about 0.6.

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The pellets were coated by spraying a coating substrate comprising tallow fat and the primary composition as prepared in example 1.

Example 5: Cosmetic for oral administration

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A composition in the form of a hard capsule has the following formulation:

Compound	mg per capsule
primary composition of example 1	500
Excipient for the core	
Microcrystalline cellulose	70
Encompress TM	60
Magnesium stearate	3
Anhydrous colloidal silica	1
Coating agent	
Gum-lac	5
Talc	61
Sucrose	250
Polyvidone	6
Titanium dioxide	0.3
Coloring agent	5

The composition can administered to the individual in an amount of 2 to 3 capsules daily.

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Claims

1. A miscible primary composition comprising at least the essential lipophilic and hydrophilic bioactive components of a whole fruit, vegetable and/or plant material, excluding insoluble fibers, in a milk or milk protein-containing carrier.

2. The primary composition according to claim 1, wherein the fruit, vegetable and/or plant material is in the form of vegetables, leaves, flowers, fruits, seeds and other parts of the plant, or a mixture thereof.

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3. The primary composition according to claim 1 or 2, wherein the fruit, vegetable or plant material is a berry such as wolfberry, blueberry, cranberry, white currant, red currant, blackcurrant, mulberry, blackberry, gooseberry, raspberry, strawberry, arbutus berry, grapes, or any other flavonoid, polyphenol or carotenoid-rich fruit, vegetables, seeds or plant materials such as apples, melons, kivi, cherries, prunes, peaches, persimmons, citrus fruits such as mandarin, orange, tangerine, grapefruit, and tomato, spinach, celery, carrots, pea, kale, parsley, watercress, cabbage, broccoli, lettuce, brussels sprouts, collard greens, turnip greens, fennel, onions, tea, corn, cocoa, thyme or sweet red pepper.

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4. The primary composition according to claim 1, wherein the essential lipophilic and hydrophilic bioactive components are lipids, alkaloids, proteins, carbohydrates, carotenoids, polyphenolic compounds such as flavonoids, vitamins or minerals.

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5. The primary composition according to claim 4, in which the flavonoids are flavones such as apigenin, luteolin or diosmetin, flavonols such as quercetin, myricetin, kaempferol, flavanones such as naringenin, and hesperidin, catechins such as epicatechin and gallocatechin, anthocyanidins such as pelargonidin, malvidin, cyanidin or isoflavones such as genistein, daidzein.

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6. The primary composition according to claim 4, in which the carotenoids are carotenes and xanthophylls such as lycopene, carotene, phytofluene, phytoene, canthaxanthin, astaxanthin, beta-cryptoxanthin, capsanthin, lutein, zeaxanthin, or those in the form of fatty acid esters.

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7. The primary composition according to claim 1, wherein the milk is from animal or plant origin.

8. The primary composition according to any of claims 1 to 7, which is in the form of a powder, gel or liquid.

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9. A process for the preparation of a composition according to claim 1, comprising the steps of:

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- i) mixing and milling the fruit, vegetable and/or plant material in milk or milk protein-containing liquid medium,
- ii) separating insoluble fibers to obtain an aqueous suspension
- iii) optionally pasteurising the resulting suspension
- iv) and further optionally drying the suspension to obtain a powder.

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10. A process for increasing miscibility or dispersibility in an aqueous system, stability, and bioavailability of bioactive compounds of a fruit, vegetable and/or a plant material using a primary composition according to one of claims 1 to 8 or process according to claim 9.

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11. An oral composition comprising the primary composition according to claims 1 to 8, in a foodstuff for oral administration, such as in a nutritional composition, a food supplement, a pet food product, a cosmetic preparation or in a pharmaceutical preparation.

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12. An oral composition according to claim 11, which is a nutritional complete formula, a dairy product, a chilled or shelf stable beverage, a mineral or purified water

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5 water, a liquid drink, a soup, a dietary supplement, a meal replacement, a nutritional bar, a confectionery, a milk or a fermented milk product, a yoghurt, a milk based powder, an enteral nutrition product, an infant formula, an infant nutritional product, a cereal product or a fermented cereal based product, an ice-cream, a chocolate, coffee, a culinary product such as mayonnaise, tomato puree or salad dressings or a pet food.

10 13. An oral cosmetic or pharmaceutical composition comprising the primary composition according to claims 1 to 8, which is a tablet, a capsule, a pill, a solution, a suspension, a syrup, a dried oral supplement, a wet oral supplement.

14. Use of a primary composition according to claim 1 to 8, for delivering the multi-nutrients of functional ingredients of fruits and plant material with improved bioavailability, miscibility and stability.

15 15. Use of a primary composition according to claim 1 to 8, for the preparation of an oral, cosmetic or pharmaceutical composition intended for improving skin health, in particular for photoprotection of the skin or for protecting skin tissue against ageing.

20 16. Use of a primary composition according to claim 1 to 8, for the preparation of an oral, topical or pharmaceutical composition intended for eye health.

25 17. Use of a primary composition according to claim 1 to 8, for the preparation of an oral, cosmetic or pharmaceutical composition intended for stimulating the immune system.

18. Use of a primary composition according to claim 1 to 8, for the preparation of an oral, cosmetic or pharmaceutical composition for preventing or treating cardiovascular diseases or disorders or cancers.

Abstract**Delivery of functional ingredients**

- 5 The present invention relates to a primary composition comprising all essential nutrients of a fruit or a plant material, which has an increased stability, bioavailability and miscibility; and process of forming the same. It also relates to an oral composition that contains the primary composition in a foodstuff, in a food supplement, in a cosmetic preparation or in a pharmaceutical preparation.

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